

REMARKS

Original claims 1-14 were pending in this application. Claims 1-10 and 12-14 have been amended, *supra*, without prejudice or admission, and new claims 15-20 have been added. Hence, claims 1-20 will be pending upon the entry of this amendment. Independent claims 1 and 3 have been amended to define claimed *Dehalococcoides* isolates of this invention according to the following unique characteristic: they are capable of using at least one of the halogenated compounds *trans*-dichloroethene and vinyl chloride as a metabolic electron acceptor. Claims 2 and 9 specify a particular, preferred *Dehalococcoides* isolate of the invention: *Dehalococcoides* isolate BAV1. Support for these amendments can be found throughout the specification as filed. For example, the specification as filed teaches, on page 9, lines 13-18, that *Dehalococcoides* isolates of the invention can transform a variety of toxic, halogenated compounds; including *trans*-dichloroethene (“*trans*-DCE”) and vinyl chloride or “VC”. *See also*, in the Examples at page 13, lines 13-15 of the specification as filed, which teaches that both vinyl chloride (“VC”) and *trans*-DCE served as growth-supporting electron acceptors for the preferred *Dehalococcoides* isolate BAV1.

Independent method claims 3 and 9 have also been amended as suggested by Examiners Deborah Ware and Mike Wityshyn during the telephonic interview of July 1, 2008. Specifically, these claims have been amended to specify that the substrate is inoculated with an “effective amount” of a *Dehalococcoides* isolate of the invention. New dependent claims 15 and 16 have been added to recite preferred embodiments of the claimed methods, in which the halogenated compound transformed by those methods is the compound vinyl chloride. New claims 17-20 have been added to recite specific halogenated compounds that can be used as metabolic electron acceptors by preferred *Dehalococcoides* isolates of the invention. Claims 17-18 recite *trans*-dichloroethene and vinyl chloride, which are specifically recited in the Markush group of claim 1 from which they depend. Claims 19-20 recite additional halogenated compounds; specifically *cis*-dichloroethene (*cis*-DCE), 1,1-dichloroethene (1,1-DCE), and vinyl bromide. Support for these compounds can be found in the specification as filed, *e.g.*, at page 9, lines 13-18; and at page 13, lines 13-15. The remaining amendments have been made to correct informalities in the recited Markush groups and other language of the original claims.

None of the amendments introduces new matter to the application. The amendments are all made without admission, and without prejudice to Applicant's right to pursue any surrendered subject matter in either this or other (*e.g.*, related divisional and other continuing) applications. Entry and consideration of these amendments are respectfully requested.

A. Applicant's Interview Summary

At the outset, Applicant thanks Examiner Deborah Ware and Supervisory Patent Examiner Mike Wityshyn for the courtesies extended during the telephonic interview of July 1, 2008 with Applicant's undersigned representative. During that interview, the rejections for enablement and indefiniteness under 35 U.S.C. § 112, first and second paragraph, and the prior art rejection under 35 U.S.C. § 102 were discussed. The Examiners agreed to reconsider the enablement and prior art rejections in view of the amendments and remarks set forth in this Response. The Examiners also indicated that the rejection for indefiniteness would be withdrawn if the independent method claims were amended to specify inoculating a substrate with an "effective amount" of the claimed *Dehalococcoides* isolate. Claims 3 and 9 have therefore been amended in accordance with the Examiners' suggestion.

**B. The Rejections Under 35 U.S.C. § 112,
First Paragraph, Should Be Withdrawn**

Claims 1-14 have been rejected under the first paragraph of 35 U.S.C. § 112 "as containing subject matter that is not described in the specification in such a way as to enable one skilled in the art ... to make and/or use the invention." *Office Action at page 2*. Applicant understands this to be a rejection under the enablement requirement of 35 U.S.C. § 112, ¶ 1 as opposed to a rejection under the "written description" requirement of that statute.

The Office Action indicates, in particular, that the microorganism recited in Applicant's claims must either be obtainable by a repeatable method set forth in the specification, or must be made readily available to the public, *e.g.*, as a microorganism deposit. In response, Applicant notes that claims 1, 3-8 and new claims 16-20, as amended, *supra*, specify microorganisms (*Dehalococcoides* isolates) defined by particular, unique characteristics: the ability to use either *trans*-dichloroethene or vinyl chloride as a metabolic electron acceptor.

Methods for obtaining isolates with these characteristics are described in the specification as filed, *e.g.*, in Example 1 at pages 10-11. Hence, a microorganism deposit is not necessary to enable the microorganisms of those claims.

Claims 2 and 9-15 specify the particular *Dehalococcoides* isolate referred to as BAV1. Applicant notes that a deposit of biological material can be made at any time before filing an application for patent or during the pendency of the application subject to a requirement for the deposit. 37 C.F.R. § 1.804(a) and M.P.E.P. § 2406. Applicant therefore respectfully declines to submit a microorganism deposit of the claimed BAV1 isolate at this time. If, however, upon a finding that the claims are otherwise in condition for allowance, the Examiner still considers such a microorganism deposit necessary, then an acceptable deposit will be made on or before the date of payment of the issue fee. *See* 37 C.F.R. § 1.809(b)(1) and M.P.E.P. § 2411.02.

In view of the foregoing, Applicant respectfully submits that the rejection under the first paragraph of 35 U.S.C. § 112 should be withdrawn.

**C. The Rejection Under 35 U.S.C. § 112,
Second Paragraph, Should Be Withdrawn**

Claims 3-14, directed to methods of “remediating a substrate,” have been rejected under the second paragraph of 35 U.S.C. § 112, as being indefinite. In particular, the Office Action indicates that these claims “fail[] to set forth clear and distinct process steps for carrying out the claimed invention” and that “the conditions are not clearly defined in the claims.” *Office Action at page 5*. During the telephonic interview, the Examiners indicated that this rejection would be withdrawn if the method claims were amended to specify that the substrate is inoculated with an “effective amount” of *Dehalococcoides* isolate. Independent claims 3 and 9 have been amended pursuant to that suggestion.

It is therefore believed that the rejection for indefiniteness has been obviated. Applicant respectfully requests that the rejection be withdrawn.

**D. The Prior Art Rejection
Should Be Withdrawn**

The original claims (claims 1-14) have also been rejected under 35 U.S.C. § 102(a), as anticipated by U.S. Patent No. 6,488,850 by Perriello *et al.* (hereinafter referred to as “Perriello” or the “Perriello patent”). According to the Office Action, Perriello anticipates Applicant’s claimed invention because:

Perriello teach[es] at page 2, second column, all lines, methods of remediating a substrate with it. The compounds remediated are halogenated compounds (*e.g.*, DCE). Also *Dehalococcoides* is disclosed

Office Action at page 5. However, Applicant respectfully submits that the Perriello patent does not teach *Dehalococcoides* whatsoever, let alone a *Dehalococcoides* isolate of the present invention, and that the rejection for anticipation over that patent should be withdrawn.

The Perriello patent actually pertains to bioremediation methods that use butane to “accelerate the transformation of aerobic conditions to anaerobic by accelerating the growth of butane-utilizing microorganisms initially in the presence of oxygen to produce carbon dioxide.” *Perriello at col. 2, lines 47-51*. Perriello lists “[s]uitable bacteria” that can be used in this process, in a table at column 7, lines 15-45 of that patent. However, *Dehalococcoides* is not listed in that table, let alone BAV1 or any other isolate capable of using either *trans*-dichloroethene or vinyl chloride as a metabolic electron acceptor. In fact, and contrary to what is asserted in the Office Action, Perriello does not mention *Dehalococcoides* at all. The passage to which the Examiner cites (the second column on page 2) is merely a list of publications cited during prosecution of the Perriello patent. Two of the cited publications happen to contain the

word “Dehalococcoides” in their titles.¹ The Perriello patent itself, however, does not specifically discuss these publications. Moreover, *Dehalococcoides* is not mentioned or discussed anywhere in Perriello’s specification.

Anticipation requires that each and every element of the rejected claim(s) be disclosed in a single prior art reference. See M.P.E.P. § 2131. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). As explained above, Perriello does not describe any isolates of *Dehalococcoides*, let alone isolates that can use *trans*-dichloroethene and/or vinyl chloride as a metabolic electron acceptor. Perriello cannot, therefore, anticipate Applicant’s pending claims. Applicant therefore respectfully requests that the rejection for anticipation over that reference be withdrawn.

E. Conclusion

For all of the foregoing reasons, it is believed that each basis for rejection of and objection to this application and its pending claims has been overcome and/or obviated. The entry and consideration of these amendments, withdrawal of all rejections and objections and allowance of the application are therefore all respectfully requested. The Examiner is invited to contact Applicant’s undersigned representatives should she conclude that there are any

¹ See, in particular, Maymó-Gatell *et al.*, “Reductive Dechlorination of Chlorinated Ethenes and 1,2-Dichloroethane by ‘*Dehalococcoides ethenogenes*’ 195,” *Applied and Environmental Microbiology* (July 1999) Vol. 65, No. 7, pages 3108-3113 (Maymó-Gatell); and Löffler *et al.*, “16S rRNA Gene-Based Detection of Tetrachloroethene-Dechlorinating *Desulfuromonas* and *Dehalococcoides* Species,” *Applied and Environmental Microbiology* (April 2000), Vol. 66, No. 4, pages 1162-1167 (“Löffler”). These are the fifth and seventh publications, respectively, cited in the right-hand column on page 2 of Perriello. Both publications are of record in the instant application. The Löffler publication is cited in Applicant’s Information Disclosure Statement (“IDS”) filed with the U.S. National Phase submission of this application on December 7, 2005. The Maymó-Gatell publication is cited in the Supplemental IDS submitted with this response.

remaining issues that could be resolved, *e.g.*, by either a Supplemental Response or an Examiner's Amendment. An allowance is earnestly sought.

Respectfully submitted,

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